P2-307 NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4

Patients with adenocarcinoma and non-smoking had better survival in chemotherapy of gemcitabine plus oral UFT for advanced non-small-cell-lung cancer previously treated with platinum

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Background: An open-label single-arm clinical study was conducted to evaluate the efficacy and toxicity of combination of gemcitabine and UFT in patients with advanced non-small-cell-lung cancer (NSCLC) after failure of previous platinum-containing regimens.

Methods: Patients with advanced NSCLC received an oral administration of UFT (tegafur 400 mg/m^2/day) from days 1 to 14 and intravenous injection of gemcitabine 900 mg/m^2 on days 8 and 15. This treatment was repeated every 3 or 4 weeks.

Results: A total of 40 patients were enrolled into this study. Eleven patients (28%; 95%CI: 14-41%) achieved a partial response. The median progression-free survival, median overall survival and 1-year survival rate were 121 days, 383 days and 50%, respectively. The most common grade 3-4 toxicity was neutropenia (38%) while the frequency of grade 3-4 non-hematologic toxicities remained at less than 5%. This combination chemotherapy demonstrated a promising effectiveness and acceptable toxicity profile for platinum-resistant NSCLC patients. A multivariate Cox regression analysis exhibited that adenocarcinoma and non-smoking habit as well as good performance status predict better survival outcome.

Conclusions: These factors could potentially bring in serious impact into results of clinical studies for second-line chemotherapy of advanced NSCLC.

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A bi-weekly administration of gemcitabine and docetaxel in patients with non-small cell lung cancer

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Background: Combination of gemcitabine and docetaxel (GEM/DOC) has shown a favorable activity with its response rate of 34-37.5%, similar to that of cisplatin and docetaxel in chemotherapy-naïve patients with stage IIIb or IV non-small cell lung cancer (NSCLC). However, neutropenia and pulmonary toxicities were related to the combination chemotherapy. Especially relatively high rate of pulmonary toxicities have been identified in monthly or weekly administration setting of both combination.

Purpose: We evaluated the feasibility and efficacy of biweekly GEM/DOC chemotherapy in patients with NSCLC.

Patients and Methods: Forty-four patients with post-operative recurrences and eighteen patients with unresectable advanced non-small cell lung cancer were enrolled in this study.

Those patients received 1000mg/m^2 of GEM and 30mg/m^2 of DOC bi-weekly, q=2 weeks. Response rate, toxicities, and completion rate are evaluated after 4 cycles. Those patients were basically treated on outpatient basis.

Results: A total of 62 patiets were treated with combination of GEM/DOC.

Patients characteristics were as follows; recurrent/unresectable: 44/18; male/female: 38/24; median age: 66.1 (range 32-80); perfomance status 0/1/2: 41/19/2; adeno/squamous/large: 45/15/2; chemo naïve/previously treated: 24/38.

A response rate was 20.7%(CR 3, PR 9, SD 34, PD 12, and NE 4). Response rates by tumor pathological type were 25% (11/44) with adenocarcinoma and 8.3% (1/12) with squamous cell carcinoma. Over grade 3 leucopenia was occurred in 17.7% (11/62), neutropenia in 32.3% (20/62), skin toxicities in 3.2% (2/62), and pulmonary toxicities in 3.2% (2/62). Treatment completion rate was 93.5%(58/62). The reasons of treatment discontinuation were pneumonia, skin rush, and angiodynia.

Conclusion: GEM/ DOC regimen is a feasible and efficacious regimen against advanced and/or recurrent NSCLC. Biweekly administration of GEM/DOC may decrease hematological toxicities and be well-tolerated regimen. In addition, the rate of pulmonary toxicities in biweekly GEM/DOC may be less compared with other scheduled combination.

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Prospective phase II trial of a combination of gemcitabine, cisplatin and UFT as first-line treatment in patients with advanced, unresectable, non-small cell lung carcinoma

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Backgroud: Most patients with advanced non-small cell lung cancer (NSCLC) receive either single agents or doublet chemotherapy. For non-elderly pts in good performance status, platinum-based double combinations represent the standard treatment. Meta-analysis have showed combination chemotherapy consisting of cisplatin plus new agent yielded a substantial survival advantage compared with carboplatin plus new agent in patients with advanced NSCLC. And oral UFT had the survival advantage in adjuvant setting. Gemcitabine may be more effective in form of fixed dose rate infusion (FDRI, 10 mg/kg/min) than conventional infusion schedule. Therefore we performed a phase II study using the combination of gemcitabine, cisplatin and UFT as a first line therapy in patients with advanced NSCLC.

Methods: Eligible patients had histologically or cytologically confirmed stage IIIB or IV NSCLC with good performance status and were chemotherapy-naive. This study was two-stage design and planned number of patients was forty-seven. Gemcitabine (1,250mg/m^2, 10mg/kg/min on days 1 and 8) and cisplatin (75mg/§/on day 1) were injected intravenously and UFT (400mg/day) was administered orally on day 1-